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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/529,759	04/18/00	VIVIER	E A33131-PCT-U

EXAMINER	
CHAKRABARTI,A	
ART UNIT	**PAPER NUMBER**
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021003
BAKER & BOTTS
30 ROCKEFELLER PLAZA
NEW YORK NY 10112

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/529,759	Applicant(s) Vivier et al.
	Examiner Arun Chakrabarti	Group Art Unit 1655

☒ Responsive to communication(s) filed on May 26, 2000 .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3 is/are rejected.

☒ Claim(s) 4-23 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Objections

1. Claims 4-23 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4-23 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as indefinite because the instantly claimed method lacks a final process step that clearly relates back to the preamble. For the method of claim 1, the preamble of the instantly claimed method is drawn to a method of documenting a repertoire of an NKR immunoreceptors, while the final process step is that of the detection of the possible hybrids formed between DNAs or cDNAs and the 3' and 5' oligonucleotide pairs and it is thus unclear as to whether the instantly claimed method is drawn to method of documenting a repertoire of an

NKR immunoreceptors, or rather the detection of the possible hybrids formed between DNAs or cDNAs and the 3' and 5' oligonucleotide pairs. Method claim requires a last step or phrase in the last step that states the accomplishments of the goals for the method which were stated in the method's preamble. Claim 1 lack such a last step and are confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashions. See Ex parte Erlich, 3 USPQ2d1011, p.1011 (Bd. Pat. Applicant. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

Claims 1-3 are rejected over the recitation of the phrases "in particular" on line 7. Regarding claim 1, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). The metes and bounds of the claims are vague and indefinite.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 1-3, the phrase "capable" on line 15 renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). The metes and bounds of the claims are vague and indefinite.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. Claim 1 is rejected over the recitation of the phrase, "functional counterpart" on line 24. It is not clear whether a biological function is claimed or chemical function is claimed or biochemical function is claimed or all of the above mentioned functions are claimed. The metes and bounds of the claims are vague and indefinite.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is rejected over the recitation of the phrase, "NKR counterpart" on line 20 and "NKR receptor counterpart" or "NKR receptor functional counterpart" on lines 22-24. It is not clear how a pair of oligonucleotides hybridize to a particular DNA and do not hybridize to the same DNA under a fixed condition. The claim is confusing because the positive and negative statements regarding hybridization is not clearly explained and therefore appears to be conflicting and self-contradictory. The metes and bounds of the claims are vague and indefinite.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is rejected over the recitation of the phrase, "the use" on line 12 and "the bringing" on line 25. The metes and bounds of the claims are vague and indefinite.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is rejected over the recitation of the phrase, "approximately" on line 19.

In absence of any specific range of approximation, it is not clear what range of temperatures are mentioned here The metes and bounds of the claims are vague and indefinite.

Claims 1-3 are indefinite and vague because the claims are written in the passive tense. Method claims should recite positive, active process steps, see Ex parte Erlich 3 USPQ 2d 1011 (BPA1 1986). This rejection may be overcome by amending the claims to recite the active tense, e.g., "providing at least one pair of oligonucleotides..", "hybridizing said DNA or cDNA populations..", "detecting hybrids formed.."

Claims 1-3 are indefinite because the claims contain information in parentheses, i.e. (20 mM tris-HCl). Parentheticals make the claims indefinite because it is unclear whether the information in the parentheses has the same, less, or more weight as the rest of the claim language. In particular, it is unclear as to whether the claims are inclusive of any buffer or require the use of the specific buffer comprising 20 mM tris-HCl, etc. Similarly, claim 3 is indefinite over the recitations of "(or respectively NKR receptor) and "(or respectively NKR receptor counterpart)".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 are rejected under 35 U.S.C. 102 (b) as being anticipated by Bottino et al. (European Journal of Immunology, (1996), Vol. 26, pages 1816-1824)

Bottino et al. teach in vitro method of documenting a repertoire of NKR immunoreceptors comprising the KIR p58 and the KAR p50 target receptors (Abstract and Introduction, Page 1816), characterized in that it comprises:

a) at least one pair of oligonucleotides, one being designated 3' oligonucleotide and the other 5' oligonucleotide, the 3' and 5' oligonucleotides of the same pair being both capable, under hybridization conditions corresponding to incubation, of hybridizing to the DNA or to the cDNA of a target NKR receptor, or NKR counterpart, but not hybridizing, under the same hybridization condition with the DNA or the cDNA of an NKR receptor counterpart, or respectively of an NKR receptor, functional counterpart of the target receptor (Abstract and Introduction, Page 1816 and MATERIALS AND METHODS Section, Identification of PAX molecule-associated transcript Subsection, Page 1820, Column 2 to Page 1822, column 1 and Figure 8). The property of being capable of hybridization to a DNA or cDNA for 1 min in a buffer [20 mM Tris-HCl, pH 8.4; 50 mM Kcl; 2.5 mM MgCl2] at a temperature of between 50 degree centigrade and 65 degree centigrade approximately, is inherently present in the primer pairs disclosed by Bottino et al.

b) mixing the DNA or cDNA populations of a biological sample of human origin for which it is desired to document the repertoire of target immunoreceptors with an excess of at least one 3' and 5' oligonucleotide pair according to (I) under conditions favorable to the

hybridization of this 3' and 5' oligonucleotide pair with the DNA or cDNAs of the biological sample (MATERIALS AND METHODS Section, Identification of PAX molecule-associated transcript Subsection, Page 1820, Column 2 to Page 1822, column 1 and Figure 8), and

c) the detection of the possible hybrids formed between these DNAs or cDNAs and the 3' and 5' oligonucleotide pair(s) (MATERIALS AND METHODS Section, Identification of PAX molecule-associated transcript Subsection, Page 1820, Column 2 to Page 1822, column 1 and Figure 8).

Bottino et al. teach in vitro method characterized in that at least one of the 3' and 5' oligonucleotide pair hybridizes to the target receptor only, not to the DNA or cDNA of a receptor (Figure 8).

Bottino et al. teach in vitro method characterized in that the 5' oligonucleotide of the 3' and 5' oligonucleotide pair used for an NKR target receptor hybridizes to the DNA or to the cDNA of an NKR receptor counterpart (Figure 8).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless--
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-3 are rejected under 35 U.S.C. 102 (a) as being anticipated by Hiby et al. (Molecular Immunology, (1997), Vol. 34, No. 5, pages 419-430).

Hiby et al. teach in vitro method of documenting a repertoire of NKR immunoreceptors comprising the KIR p58 and the KAR p50 target receptors (Abstract and Table 2) characterized in that it comprises:

a) at least one pair of oligonucleotides, one being designated 3' oligonucleotide and the other 5' oligonucleotide, the 3' and 5' oligonucleotides of the same pair being both capable, under hybridization conditions corresponding to incubation, of hybridizing to the DNA or to the cDNA of a target NKR receptor, or target NKR counterpart, but not hybridizing, under the same hybridization condition with the DNA or the cDNA of an NKR receptor counterpart, or respectively of an NKR receptor, functional counterpart of the target receptor (Abstract and Table 3 and Page 425, column 1, second and third paragraph). The property of being capable of hybridization to a DNA or cDNA for 1 min in a buffer [20 mM Tris-HCl, pH 8.4; 50 mM Kcl; 2.5 mM MgCl2] at a temperature of between 50 degree centigrade and 65 degree centigrade approximately, is inherently present in the primer pairs disclosed by Bottino et al.

b) mixing the DNA or cDNA populations of a biological sample of human origin for which it is desired to document the repertoire of target immunoreceptors with an excess of at least one 3' and 5' oligonucleotide pair according to (I) under conditions favorable to the hybridization of this 3' and 5' oligonucleotide pair with the DNA or cDNAs of the biological sample (Abstract and Table 3 and Page 423, column 2, last paragraph to page 425, third paragraph and Figure 2), and

c) the detection of the possible hybrids formed between these DNAs or cDNAs and the 3' and 5' oligonucleotide pair(s) (Abstract and Table 3 and Page 423, column 2, last paragraph to page 425, third paragraph and Figure 2).

Hiby et al. teach in vitro method characterized in that at least one of the 3' and 5' oligonucleotide pair hybridizes to the target receptor only, not to the DNA or cDNA of a receptor (Page 423, column 2, last paragraph to page 425, third paragraph and Figure 2).

Hiby et al. teach in vitro method characterized in that the 5' oligonucleotide of the 3' and 5' oligonucleotide pair used for an NKR target receptor hybridizes to the DNA or to the cDNA of an NKR receptor counterpart (Page 423, column 2, last paragraph to page 425, third paragraph and Figure 2).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center

located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Kr. Chakrabarti

Arun Chakrabarti
Patent Examiner
Art Unit 1655

December 18, 2000

Carla Myers

CARLA J. MYERS
PRIMARY EXAMINER